



Department of Hematology Oncology

## **Study Title for Study Participants: Southern Lung Cancer Study**

**Official Study Title for Internet Search On [Http://Www.Clinicaltrials.Gov](http://www.Clinicaltrials.gov):  
WF 01414: Improving Resection Rates Among African Americans With NSCLC  
(Non-Small Cell Lung Cancer)  
(Southern Lung Cancer Study)**

### **What is the usual approach to my possible or proven early stage lung cancer?**

Lung resection (surgery) is the standard-of-care in medically fit patients with early stage lung cancer, and multiple studies have shown that improvements in lung resection rates translate into improvements in overall survival. Recently, focused radiation therapy given over a few doses has been established as an alternative mode of potentially curative treatment in patients with biopsy-proven, early stage lung cancer who are deemed not eligible for surgery.

### **What are my other choices if I do not take part in this study?**

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above or
- you may choose to take part in a different study, if one is available.

### **Why is this study being done?**

African American patients with early stage lung cancer seem to undergo surgery/radiation less often and for unclear reasons; we are doing this study to determine if a patient navigator increases rates of surgery/radiation in these patients. The purpose of this study is to see if there is an improvement in the rates of lung resection or focused radiation therapy given in low doses in African Americans in the United States (US) with recently diagnosed (i.e., within 70 days of study enrollment), clinically suspicious or biopsy-proven, early stage, lung cancer by including patient navigator compared to usual care. A patient navigator helps patients find the information they need to make informed decisions and links patients with needed resources to overcome barriers to treatment. Approximately 200 participants eligible for analysis will be enrolled in this study.

## What are the Study Groups?

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will be “randomized” into one of the two study groups: Usual Care Group or Intervention Group. For this study, randomization happens at the site level, meaning that this site has been randomized into one of these groups by chance. Neither you nor your doctor can choose the group you will be in. Patients in the Usual Care Group will receive the usual care that is provided for patients diagnosed with probable/proven, early-stage lung cancer. Patients in the intervention group will receive the usual care that is provided for patients diagnosed with probable/proven, early-stage lung cancer, as well as a study-specific, patient navigation.

### ***Both groups will receive standard of care for lung cancer:***

Standard care for patients diagnosed with probable/proven, early-stage lung cancer may include the following: non-surgical staging work-up (including scans and endoscopies), consultation with a general or cardiothoracic surgeon, consultation with a radiation oncologist, consultation with a medical oncologist, consultation with heart or lung specialist, surgical staging, surgical resection or stereotactic body radiation therapy, and postoperative treatment (chemotherapy and/or radiation therapy), as medically indicated.

### ***If you are in the Usual Care Group:***

Your health care team will provide you with support and education on an as needed basis and meet your needs as they arise.

Study site coordinators *will not* interact with study participants beyond what is considered usual care at each study site (which may or may not include various levels of “patient navigation”), other than to review patients' medical records for study purposes.

### ***If you are in the Intervention Group:***

Your health care team will provide you with support and education on an as needed basis and meet your needs as they arise.

Within a week after signing this consent form, you will be introduced to a Patient Navigator who will give you a copy of a booklet about lung cancer and its treatment. It may be given to you in person or mailed to your home. Your Patient Navigator will connect with you at least weekly by phone, email, or in-person. Your Patient Navigator will help to identify resources to address your healthcare-related needs.

Your Patient Navigator will call you at least weekly for the first 4 months or until you undergo surgical resection or stereotactic body radiation therapy for your lung cancer. In addition to the telephone calls, you may meet with your Patient Navigator face-to-face and/or by email. You and your Patient Navigator will decide which type(s) of meeting(s) will work best for you.

***If you are in the Usual Care or the Intervention Group:***

All of the study procedures described below are being done specifically for the study. This study does not involve medical treatment – all standard medical/surgical care for your lung cancer will take place outside of the study. If you agree to be in this study, the following will happen:

Research staff will call you to administer a baseline survey by telephone. The baseline survey will collect data including

- your employment status,
- marital status,
- education level,
- income level.

The survey will have questions about

- your quality of life,
- anxiety level,
- how confident you feel in your ability to communicate with health care providers,
- trust in physicians,
- intention to receive lung surgery,
- satisfaction with your decision,
- risk attitude,
- cancer beliefs,
- social support,
- fatalism,
- faith,
- barriers,
- comorbidity,
- smoking frequency.

A research staff member will call you to administer a similar survey at 3 months, 6 months, and 12 months after enrollment. This survey will take approximately 45 minutes. An additional brief questionnaire will be administered at 9 months. It will take about 15 minutes to complete.

Data will be collected from you and from your medical records for purposes of the study.

This may include:

- date of birth,
- gender,
- race,
- ethnicity,
- lung cancer diagnosis,
- date of diagnosis,
- person who made diagnosis,
- stage of cancer,
- related clinical visits and dates,

- related treatment and dates,
- referring physician and site information,
- comorbidities,
- study outcomes,
- contact information including phone numbers and address.

Medical release forms will be used as required.

Data may also include a review of outpatient records and emergency department records, including:

- personal history,
- medical history,
- surgical history,
- family history,
- social history,
- medication history,
- allergies,
- physical examination results,
- laboratory and tissue biopsy findings and specimens,
- radiographic results,
- assessments and plans by your care provider(s).

## **How long will I be in this study?**

Participation in the study will take about 12 months.

## **What extra tests and procedures will I have if I take part in this study?**

If you decide to take part, you will be asked to sign this consent form.

You will be asked to complete 4 surveys and one additional brief questionnaire. Each survey will be administered by telephone. Each phone call will last approximately 45 minutes with the exception of a 15 minute call at 9 months.

If after study enrollment (but before surgery) you are found *not* to have lung cancer or have late stage lung cancer, your participation in the study will end.

## **What possible risks can I expect from taking part in this study?**

There are minimal physical or psychological risks or discomforts associated with this study. It is possible but unlikely that some of the survey questions could pose minor psychological discomfort related to survey questions. To protect against this risk you can choose to not respond to any questions or to terminate participation at any point. If at any point during the course of the study, you become agitated, emotionally distressed, or

otherwise indicate the need for clinical mental health intervention, you will be referred to appropriate clinical mental health resources at your study site.

You might worry about someone sharing information you provided during the surveys to unauthorized people. Procedures are in place to protect your information from being released to unauthorized people. Only research staff directly involved with the study will have access to study information.

- You may lose time at work or home and spend more time in the doctor's office than usual when completing the study questionnaires
- You may be asked sensitive or private questions which you normally do not discuss
- Although risks are minimal, unforeseeable or unexpected risks may occur.

### **What possible benefits can I expect from taking part in this study?**

It is unknown whether adding patient navigation will increase rates of surgical resection or stereotactic radiation therapy. There may be no other direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours/will help the researcher learn more about improving rates of surgical resection or radiosurgery for lung cancer in patients with probable or proven lung cancer.

### **Can I stop taking part in this study?**

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

### **What are my rights in this study?**

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Wake Forest Baptist Health Institutional Review Board at [REDACTED].

### **What are the costs of taking part in this study?**

There are no costs to you for participating in this study. All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

### **Will I be compensated for this study?**

You will receive a \$50 gift card at each assessment period (baseline, 3 months, 6 months, and 12 months).

### **Who will see my medical information?**

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: type of lung cancer, diagnosis date, type and date of cancer treatment(s), name and dosage of medications used in the past month.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

- 1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research
- 2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center
- 3) The National Cancer Institute.
- 4) Investigators located at the Medical University of South Carolina (MUSC) involved in this research study and designated staff administering the telephone surveys and brief questionnaire.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. You can tell Dr. Kathryn E. Weaver that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Kathryn E. Weaver, Ph.D, MPH.




However, if you take away permission to use your Protected Health Information, you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study. By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest Baptist Health will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

### **Where can I get more information?**

The National Cancer Institute will obtain information from this clinical trial under data collection authority Title 42 U.S.C. 285.



A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor Dr. Kathryn Weaver at [REDACTED] (M-F, 8am-5pm) and after hours at [REDACTED].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [REDACTED].

You will be given a copy of this signed consent form.

## My Signature Agreeing to Take Part in the Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the study.

\_\_\_\_\_  
Participant's signature

\_\_\_\_\_  
Participant's printed name

\_\_\_\_\_  
Date of signature

\_\_\_\_\_  
Time

am/pm

\_\_\_\_\_  
Signature of person(s) obtaining informed consent:

\_\_\_\_\_  
Date of signature

\_\_\_\_\_  
Time

am/pm